

**JD07 Rec'd PCT/PTO 03 JAN 2002**

FORM PTO-1390 (Modified) (REV 11-2000)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER <b>112843-037</b>
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR) <b>10/019964</b>

INTERNATIONAL APPLICATION NO. <b>PCT/EP00/06362</b>	INTERNATIONAL FILING DATE <b>05 July 2000</b>	PRIORITY DATE CLAIMED <b>06 July 1999</b>
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TITLE OF INVENTION  
**GELLED NUTRITIONAL COMPOSITION AND PROCESS**

APPLICANT(S) FOR DO/EO/US  
**Fuchs et al.**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
  - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

**Items 13 to 20 below concern document(s) or information included:**

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

**Express Mail No.: EL 727 381 284 US**  
**Return Receipt Postcard**

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.101) <b>10/019964</b>		INTERNATIONAL APPLICATION NO. <b>PCT/EP00/06362</b>		ATTORNEY'S DOCKET NUMBER <b>112843-037</b>	
24. The following fees are submitted: <b>BASIC NATIONAL FEE ( 37 CFR 1.492 (a) (1) - (5) ) :</b> <input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... <b>\$1040.00</b> <input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... <b>\$890.00</b> <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... <b>\$740.00</b> <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... <b>\$710.00</b> <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) ..... <b>\$100.00</b> <div style="text-align: right;"><b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b></div>				<b>CALCULATIONS PTO USE ONLY</b>  <div style="border: 1px solid black; height: 100px; width: 100%;"></div>	
Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).				<b>\$0.00</b>	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	24 - 20 =	4	x \$18.00	<b>\$72.00</b>	
Independent claims	4 - 3 =	1	x \$84.00	<b>\$84.00</b>	
Multiple Dependent Claims (check if applicable).			<input type="checkbox"/>	<b>\$0.00</b>	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$1,046.00</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2.				<b>\$0.00</b>	
<b>SUBTOTAL =</b>				<b>\$1,046.00</b>	
Processing fee of <b>\$130.00</b> for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				<b>\$0.00</b>	
<b>TOTAL NATIONAL FEE =</b>				<b>\$1,046.00</b>	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).			<input type="checkbox"/>	<b>\$0.00</b>	
<b>TOTAL FEES ENCLOSED =</b>				<b>\$1,046.00</b>	
				<b>Amount to be:</b>	\$
				<b>refunded</b>	
				<b>charged</b>	\$
a. <input checked="" type="checkbox"/> A check in the amount of <b>\$1,046.00</b> to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <b>02-1818</b> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.					
<b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b>					
<b>SEND ALL CORRESPONDENCE TO:</b> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <b>Robert M. Barrett, Esq.</b>  <b>Bell, Boyd &amp; Lloyd LLC</b>  <b>P.O. Box 1135</b>  <b>Chicago, Illinois 60690-1135</b>  <b>Tel: (312) 807-4204</b> </div>					
				 SIGNATURE <b>Robert M. Barrett</b> NAME <b>30,142</b> REGISTRATION NUMBER <b>January 3, 2002</b> DATE	

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Fuchs et al.  
Appl. No.: PCT/EP00/06362  
Filed: Filed Herewith  
Title: GELLED NUTRITIONAL COMPOSITION AND PROCESS  
Art Unit: Unknown  
Examiner: Unknown  
Docket No.: 112843-037

Commissioner for Patents  
Washington, DC 20231

**PRELIMINARY AMENDMENT**

Sir:

Please amend the above-identified patent application as follows:

**In the Claims:**

Please cancel Claims 1-29 without prejudice or disclaimer.

Please add newly-submitted Claims 30-54 as follows:

30. A gelled nutritional composition comprising a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins; in which gelled nutritional composition the protein source provides 10% to 25% of the energy of the composition and the carbohydrate source provides 60% to 95% of the energy of the composition.

31. A gelled nutritional composition according to claim 30 which is a clear gel.

32. A gelled nutritional composition according to claim 30 which provides 30% to 100% of the recommended daily allowance of vitamins and minerals per 1000 kcal (4187 kJ).

33. A gelled nutritional composition according to claim 30 which has an energy density of 800 kcal/l to 1200 kcal/l (3350 kJ/l to 5024 kJ/l).

34. A gelled nutritional composition according to claim 30 which has a viscosity of 5000 cp to 40000 cp.

35. A gelled nutritional composition according to claim 30 in which the carbohydrate source provides 75% to 90% of the energy of the composition.

36. A gelled nutritional composition according to claim 30 which has a pH of 3.5 to 4.1.

37. A gelled nutritional composition according to claim 30 which is in the form of a clear gel.

38. A gelled nutritional composition according to claim 37 which provides 30% to 100% of the recommended daily allowance of vitamins and minerals per 1000 kcal (4187 kJ).

39. A gelled nutritional composition according to claim 37 which has an energy density of 800 kcal/l to 1200 kcal/l (3350 kJ/l to 5024 kJ/l).

40. A gelled nutritional composition according to claim 37 which has a viscosity of 5000 cp to 40000 cp.

41. A gelled nutritional composition according to claim 37 in which the carbohydrate source provides 75% to 90% of the energy of the composition.

42. A gelled nutritional composition according to claim 37 which has a pH of 3.5 to 4.1.

43. A gelled nutritional composition according to claim 40 which provides 30% to 100% of the recommended daily allowance of vitamins and minerals per 1000 kcal (4187 kJ).

44. A gelled nutritional composition according to claim 40 which has an energy density of 800 kcal/l to 1200 kcal/l (3350 kJ/l to 5024 kJ/l).

45. A gelled nutritional composition according to claim 40 in which the carbohydrate source provides 75% to 90% of the energy of the composition.

46. A gelled nutritional composition according to claim 40 which has a pH of 3.5 to 4.1.

47. A method of providing nutrition to a patient suffering from dysphagia, the method comprising administering to the patient a gelled nutritional composition which contains a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins.

48. A method according to claim 47 in which the gelled nutritional composition is a clear gel.

49. A method according to claim 47 in which the gelled nutritional composition provides 30% to 100% of the recommended daily allowance of vitamins and minerals per 1000 kcal (4187 kJ).

50. A method according to claim 47 in which the gelled nutritional composition has an energy density of 800 kcal/l to 1200 kcal/l (3350 kJ/l to 5024 kJ/l).

51. A method according to claim 47 in which the gelled nutritional composition has a viscosity of 5000 cp to 40000 cp.

52. A method according to claim 47 in which the protein source provides 10% to 25% of the energy of the gelled nutritional composition.

53. A method according to claim 47 in which the carbohydrate source provides 75% to 90% of the energy of the gelled nutritional composition.

54. A method for providing supplemental nutrition to a child, the method comprising administering to the child a gelled nutritional composition which contains a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins.

#### REMARKS

This Preliminary Amendment is submitted in the above-identified patent application. Pursuant to the Preliminary Amendment, Claims 1-29 have been canceled and newly-submitted

Appl. No. PCT/EP00/06362

Claims 30-54 have been added. This Preliminary Amendment does not add new subject matter. Applicants also note for the record that the purpose of this Preliminary Amendment is to place the claims in proper format and Applicants do not intend to disclaim any subject matter in view of this Preliminary Amendment.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Versions with Markings to Show Changes Made.**"

Respectfully submitted,

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BY 

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE****In the Claims:**

Please cancel Claims 1-29 without prejudice or disclaimer.

Please add newly-submitted Claims 30-54 as follows:

30. A gelled nutritional composition comprising a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins; in which gelled nutritional composition the protein source provides 10% to 25% of the energy of the composition and the carbohydrate source provides 60% to 95% of the energy of the composition.

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53. A method according to claim 47 in which the carbohydrate source provides 75% to 90% of the energy of the gelled nutritional composition.

54. A method for providing supplemental nutrition to a child, the method comprising administering to the child a gelled nutritional composition which contains a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins.

## Gelled Nutritional Composition and Process

### Field of the Invention

5 This invention relates to a gelled nutritional composition which may provide a nutritional supplement; for example for dysphagia patients and children. The invention also relates to a process for producing the gelled nutritional composition and to a method for providing nutrition to a dysphagic patient.

### Background of the Invention

10 Many people do not take in sufficient nutrients for a nutritionally complete diet. In order to assist these people, nutritional supplements have been developed. Nutritional supplements are not intended to provide all the nutrients necessary for a nutritionally complete diet; instead they are intended to supplement the diet such that it becomes more nutritionally complete.

15 There are many targets for nutritional supplements; for example children, the elderly and patients suffering for dysphagia. Dysphagia, the feeling of difficulty in swallowing, is common in all age groups but is especially prevalent amongst the elderly. Typical symptoms may include drooling, a feeling that food is sticking in the throat, discomfort in the chest or throat, a feeling of a lump in the throat, and coughing or choking caused by food not passing easily to the stomach and being sucked into the lungs.

20 Dysphagia may be caused by many factors. For example, simple causes may be poor teeth, ill-fitting dentures, influenza, or gastroesophageal reflux. Other more serious causes include strokes, progressive neurological disorders, the presence of tracheotomy tubes, paralyzed vocal cords, tumors or surgery to the head, neck or esophageal areas.

25 Ordinarily, for most people, the condition clears up itself reasonably rapidly or may be easily treated by having appropriate dental work done. However, for more serious cases, the condition may not be easily remedied. In these cases, the patient often suffers weight loss and other complications of inadequate nutrition and liquid intake.

30 It is generally found that patients suffering from dysphagia are able to better swallow more viscous foods and drinks. Therefore it has been suggested to add

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viscosity increasing agents to drinks and liquid foods to assist dysphagia patients with swallowing. For example, Japanese patent application 5-38262 describes an agent which is made up of alpha-lized starch and dextrin. The agent may be added to liquid foods to thicken them without changing the color, taste and flavor of the liquid foods. Further, soluble coffee powders which provide thickened coffee beverages are available on the market under the trade name RESOURCE (Novartis Nutrition). These powders contain modified starches to provide the coffee beverage with a "honey-like" consistency.

However, there is still a need for nutritional compositions which may be more readily consumed by dysphagia patients and are of high nutritional value.

Further, for patients in general who require nutritional supplementation, taste fatigue is a common problem; especially among children and the elderly. Nutritional supplements with new and interesting organoleptic properties and appearances are constantly needed to deal with the problem. In particular, nutritional supplements which do not have a milky appearance and taste are extremely desirable. In order to meet this need, nutritional supplements in the form of fruit juices are described in European patent application 0486425 and US patent 5,641,531. However, these products are not ideally suited to dysphagia patients. Further, nutritional supplements with other organoleptic properties and appearances are needed.

Therefore an object of this invention is to provide a nutritional composition which is suitable for dysphagia patients and which has a gelled consistency.

#### Summary of the Invention

Accordingly, in one aspect, this invention provides gelled nutritional composition comprising a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins.

The gelled nutritional composition is preferably in the form of a clear gel. Further, the gelled nutritional composition preferably provides about 30% to about 100% of the recommended daily allowance of vitamins and minerals per 1000 calories. The energy density is preferably about 800 kcal/l to about 1200 kcal/l.

The viscosity of the gelled nutritional composition is preferably about 5000 cp to about 40000 cp.

In another aspect, this invention provides a method of providing nutrition to a patient suffering from dysphagia, the method comprising administering to the patient a gelled nutritional composition which contains a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins.

5 In a further aspect, this invention provides a method for providing supplemental nutrition to a child, the method comprising administering to the child a gelled nutritional composition which contains a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins.

### 10 Detailed Description of Preferred Embodiments of the Invention

Embodiments of the invention are now described by way of example only. This invention provides a nutritional composition which is in the form of a gel. The composition contains a protein source which includes gelled whey protein; a carbohydrate source; minerals; and vitamins. The nutritional composition is ideally suited as a nutritional supplement; especially for children and dysphagia patients.

15 The protein source includes whey protein. The whey protein may be any commercially available whey protein source which is in substantially intact form. Preferably, however, the whey protein is a whey protein isolate. Whey protein isolates contain more than 90% by weight of whey protein. Suitable whey protein isolate sources include ALACEN 895 (New Zealand Milk Products Inc), BiPRO (Le Sueur Isolates of Le Sueur, Minnesota), PROVON-190 (Avonmore Ingredients Inc of Monroe Wisconsin) and LACPRODAN 9212 (Royal Proteins, Inc of Rosemont Illinois).

20 The protein source may, if desired, include minor amounts of other suitable types of protein. For example, the protein source may further include minor amounts of casein protein, soy protein, rice protein, pea protein, carob protein, oat protein, caseino-glyco-macropetide or mixtures of these proteins. Further, if desired, the protein source may further include minor amounts of free amino acids. The other suitable types of protein preferably comprise less than about 20 % by weight of the protein source; more preferably less than about 10% by weight. Most other types of protein do not provide a clear gel and hence the protein source preferably contains little or no protein other than whey protein.

30 The protein source preferably provides about 5% to about 40% of the energy of the nutritional composition. More preferably, the protein source

provides about 10% to about 25% of the energy of the nutritional composition; for example about 14% to about 16%. In terms of weight, the protein preferably provides about 1% to about 5% by weight of the nutritional composition.

5 The nutritional composition also includes a carbohydrate source. The carbohydrate source preferably provides about 60% to about 95% of the energy of the nutritional composition. More preferably, the carbohydrate source provides about 75% to about 90% of the energy of the composition; for example about 84% to about 86%. In terms of weight, the carbohydrate preferably provides about 10% to about 25% by weight of the nutritional composition.

10 Any suitable carbohydrate source may be used including maltodextrin, starch including modified starch, glucose, fructose, corn syrup and sucrose, or mixtures thereof. Preferably the carbohydrate source is free from lactose. If the nutritional composition contains fruit juices, the carbohydrates in the fruit juice form part of the carbohydrate source.

15 A preferred carbohydrate source is a mixture of maltodextrin and sucrose or high fructose corn syrup, or both. The maltodextrin preferably has a dextrose equivalent (DE) of at least about 10 but maltodextrins having a DE below 10 would also work. Preferably the DE of the maltodextrin is about 15. The carbohydrate source preferably comprises about 20% to about 50% by weight of maltodextrin and about 50% to about 80% by weight of sucrose or high fructose corn syrup, or both.

20 The nutritional composition may include a lipid source but preferably does not. The addition of a lipid source to the nutritional composition will result in a gel which is not totally clear. However, if this is acceptable, a lipid source may be added. If a lipid source is added, it preferably provides about 1% to about 50% of the energy of the nutritional composition; more preferably about 1% to about 10%. Suitable lipid sources include vegetable oils such as safflower oil, corn oil, canola oil, soybean oil and olive oil.

25 The nutritional composition preferably includes a substantially complete vitamin and mineral profile. For example, sufficient vitamins and minerals may be provided to supply about 30% to about 250% of the US recommended daily allowance of the vitamins and minerals per 1000 calories of the nutritional composition; more preferably about 30% to about 100%. Suitable ranges for vitamins and minerals are as follows:

35

Nutrient	Range per 100 g	Preferred range per 100 g
Sodium	10 to 50 mg	25 to 35 mg
Potassium	10 to 50 mg	25 to 35 mg
Calcium	20 to 270 mg	40 to 60 mg
Magnesium	0 to 108 mg	10 to 30 mg
Phosphorus	20 to 270 mg	85 to 105 mg
Iron	0 to 4.9 mg	0.5 to 1.0 mg
Copper	0 to 0.54 mg	0.05 to 0.20 mg
Zinc	0 to 4 mg	0.80 to 1.10 mg
Manganese	0 to 500 µg	100 to 200 µg
Chromium	0 to 32.4 µg	1 to 2.5 µg
Molybdenum	0 to 20.25 µg	2 to 10 µg
Selenium	0 to 18.9 µg	1 to 5 µg
Iodine	0 to 41 µg	2 to 10 µg
Vitamin C	0 to 16.2 mg	5 to 15 mg
Vitamin B1	0 to 0.4 mg	0.05 to 0.2 mg
Vitamin B2	0 to 0.46 mg	0.05 to 0.2 mg
Niacin	0 to 5.4 mg	1 to 2 mg
Vitamin B6	0 to 0.54 mg	0.1 to 0.3 mg
Vitamin B12	0 to 1.62 µg	0.2 to 0.6 µg
Pantothenic acid	0 to 2.7	0.5 to 1 mg
Folic acid	0 to 108 µg	10 to 50 µg
Biotin	0 to 81 µg	10 to 30 µg
Vitamin A	0 to 331.8 IU	150 to 300 IU
β-carotene	0 to 0.1 mg	0.05 to 0.09 mg
Vitamin D3	0 to 28.06 IU	10 to 25 IU
Vitamin E	0 to 2.31 IU	1 to 2 IU
Vitamin K	0 to 4.01 µg	2 to 3 µg
Choline	0 to 26.1 mg	20 to 25 mg
Taurine	0 to 4.99 mg	4 to 4.5 mg

The nutritional composition preferably has an energy content of about 800 kcal/l to about 1200 kcal/l; for example an energy content of about 1000 kcal/l.



The nutritional composition preferably has a pH in the range of about 3.5 to about 4.1. Therefore food grade acidifying agents are preferably included. Examples of suitable acidifying agents include food grade citric acid, malic acid, HCl, phosphoric acid, or mixtures of these acids. Mixtures of malic and phosphoric and citric and phosphoric are particularly preferred. If a fruit juice is included in the nutritional composition, the fruit juice will also provide some acidifying agents.

The nutritional composition may include flavors as desired. If a fruit juice is included in the nutritional composition, the fruit juice will provide flavor. However artificial flavors may also be used; either alone or in addition to natural flavors.

The nutritional composition preferably has a viscosity above about 5000 cp; more preferably about 8000 cp to about 40000 cp. If a soft gel is desired, viscosities in the range of about 10000 cp to about 15000 are ideal. For pudding-like products, viscosities in the range of about 30000 cp to about 38000 cp are desirable.

The nutritional composition may be produced by suspending the protein source in water under stirring. The carbohydrate source, the lipid source if used, the vitamins and minerals, acidifying agents, flavors, and colors may then be added to provide a liquid mixture. Commercially available liquefiers may be used to form the liquid mixture. The temperature of the liquid mixture may be room temperature but high temperatures may also be used if desired.

The liquid mixture is then standardized to provide a desired solids content; for example of about 20% to about 28% by weight. More preferably, the solids content is about 24% to about 26%. The pH may be standardized to about 3.5 to about 4.1.

If the liquid mixture contains lipids, the mixture may then be homogenized; for example in two stages at about 7 MPa to about 40 MPa in the first stage and about 2 MPa to about 14 MPa in the second stage. If not done prior to homogenization, the pH and solids content of the homogenized mixture may be standardized at this point. Homogenization is not necessary for products which do not contain lipids.

The homogenized mixture is then filled into containers and gelled. This may be accomplished in many ways. For example, the homogenized mixture may be rapidly heated to about 90 to 95°C in a plate heat exchanger and then hot filled into containers. The containers are sealed and held at a temperature of at

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least about 80°C for a time sufficient to complete gelling of the whey protein; for example for about 5 to 10 minutes. The containers are then cooled to ambient temperature to provide a gelled nutritional composition.

5 Alternatively, the homogenized mixture may be filled into containers at ambient temperature. The containers are sealed and then heated to a temperature of at least about 80°C for a time sufficient to gel the whey protein; for example for about 10 to 20 minutes. The containers are then cooled to ambient temperature to provide a gelled nutritional composition.

10 The nutritional compositions may be used as nutritional supplements for dysphagia patients. The amount of the nutritional composition required to be consumed by a patient will vary depending upon factors such as the patient's condition, the patient's body weight, the age of the patient, and other sources of nutrition. However the required amount may be readily set by a medical practitioner or nutritionist.

15 Similarly, the nutritional compositions may be used as nutritional supplements in general; especially for children. The amount of the nutritional composition required to be consumed is not critical.

20 The nutritional compositions may also be used as nutritional supplements for athletes. In this form, the nutritional compositions are preferably packaged into squeeze packs which are easy to handle and use when active.

Specific examples of the invention are now described by way of further illustration.

#### 25 Example 1

Water at room temperature is placed in a batch mixing tank and stirred at a moderate speed. Whey protein isolate (ALACEN 895) is added to the water. A carbohydrate mixture of maltodextrin (DE 15), a sweetener and optionally a starch is added to solution under stirring. Minerals are then added. The solution is then acidified to a pH of about 3.6 using an acid mixture of malic acid and phosphoric acid and fruit juices. Flavors, colors and vitamins are then added. The solids content of the solution is then standardized to the desired level if necessary.

35 The solution is then rapidly heated to about 90 to 95°C in a plate heat exchanger and hot filled into containers. The containers are sealed and held at a temperature of at least about 80°C for about 5 to 10 minutes. The products are

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then cooled to ambient temperature. The composition of the products is as follows:

Nutrient	Concentration (weight %)
Whey protein isolate	2 - 4.5
Carbohydrates	11 - 20
Maltodextrin	5 - 8
Starch	0 - 1
Sucrose and/or high fructose corn syrup.	6 - 11
Fruit Juice	5 - 50

5

The vitamin and mineral profile of the products is as follows:

Nutrient	Amount per 100 g
Sodium	28 mg
Potassium	28 mg
Calcium	50 mg
Magnesium	20 mg
Phosphorus	94 mg
Iron	0.84 mg
Copper	0.10 mg
Zinc	0.93 mg
Manganese	141 µg
Chromium	1.7 µg
Molybdenum	6.2 µg
Selenium	3.1 µg
Iodine	6.75 µg
Vitamin C	11.25 mg
Vitamin B1	0.11 mg
Vitamin B2	0.14 mg
Niacin	1.46 mg
Vitamin B6	0.2 mg
Vitamin B12	0.42 µg
Pantothenic acid	0.74
Folic acid	28.14 µg
Biotin	22 µg
Vitamin A	225 IU
β-carotene	0.07 mg
Vitamin D3	18.75 IU
Vitamin E	1.52 IU
Vitamin K	2.64 µg
Choline	23.92 mg
Taurine	4.22 mg

The products have a solids concentration of about 24 to about 26% by weight and a pH of about 3.5 to about 4.1. The products are in the form of a

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clear gel. The energy density of the products is 1000 kcal/l. The viscosities range from about 10000 cp to about 35000 cp when measured using a Brookfield LV-1 viscometer with a No 4 spindle at 12 rpm.

5     Example 2

10     The process of example 1 is repeated except that the homogenized solution is filled into containers at ambient temperature. The containers are sealed and held at a temperature of at least about 80°C for about 10 to 20 minutes. The products are then cooled to ambient temperature.

15     The products have a solids concentration of about 24 to about 26% by weight and a pH of about 3.5 to about 4.1. The products are in the form of a clear gel. The energy density of the products is 1000 kcal/l. The viscosities range from about 10000 cp to about 35000 cp when measured using a Brookfield LV-1 viscometer with a No 4 spindle at 12 rpm.

Example 3

20     A nutritional composition produced according to example 1 and which has a viscosity of about 35000 is given to an elderly patient suffering from a swallowing disorder. The patient is able to consume the nutritional supplement without great difficulty and much easier than liquids. Further the patient finds the product to have a good mouthfeel.

We Claim

1. A gelled nutritional composition comprising a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins.
2. A gelled nutritional composition according to claim 1 which is a clear gel.
3. A gelled nutritional composition according to claim 1 which provides about 30% to about 100% of the recommended daily allowance of vitamins and minerals per 1000 calories.
4. A gelled nutritional composition according to claim 1 which has an energy density of about 800 kcal/l to about 1200 kcal/l.
5. A gelled nutritional composition according to claim 1 which has a viscosity of about 5000 cp to about 40000 cp.
6. A gelled nutritional composition according to claim 1 in which the protein source provides about 10% to about 25% of the energy of the composition.
7. A gelled nutritional composition according to claim 1 in which the carbohydrate source provides about 75% to about 90% of the energy of the composition.
8. A gelled nutritional composition according to claim 1 which has a pH of about 3.5 to about 4.1.
9. A gelled nutritional composition in the form of a clear gel, the composition comprising a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins.
10. A gelled nutritional composition according to claim 9 which provides about 30% to about 100% of the recommended daily allowance of vitamins and minerals per 1000 calories.

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11. A gelled nutritional composition according to claim 9 which has an energy density of about 800 kcal/l to about 1200 kcal/l.

5 12. A gelled nutritional composition according to claim 9 which has a viscosity of about 5000 cp to about 40000 cp.

13. A gelled nutritional composition according to claim 9 in which the protein source provides about 10% to about 25% of the energy of the composition.

10 14. A gelled nutritional composition according to claim 9 in which the carbohydrate source provides about 75% to about 90% of the energy of the composition.

15 15. A gelled nutritional composition according to claim 9 which has a pH of about 3.5 to about 4.1.

20 16. A gelled nutritional composition in the form of a clear gel, the composition comprising a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins; and the composition having a viscosity of about 5000 cp to about 40000 cp.

25 17. A gelled nutritional composition according to claim 16 which provides about 30% to about 100% of the recommended daily allowance of vitamins and minerals per 1000 calories.

18. A gelled nutritional composition according to claim 16 which has an energy density of about 800 kcal/l to about 1200 kcal/l.

30 19. A gelled nutritional composition according to claim 16 in which the protein source provides about 10% to about 25% of the energy of the composition.

35 20. A gelled nutritional composition according to claim 16 in which the carbohydrate source provides about 75% to about 90% of the energy of the composition.

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21. A gelled nutritional composition according to claim 16 which has a pH of about 3.5 to about 4.1.

5 22. A method of providing nutrition to a patient suffering from dysphagia, the method comprising administering to the patient a gelled nutritional composition which contains a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins.

10 23. A method according to claim 22 in which the gelled nutritional composition is a clear gel.

24. A method according to claim 22 in which the gelled nutritional composition provides about 30% to about 100% of the recommended daily allowance of vitamins and minerals per 1000 calories.

15 25. A method according to claim 22 in which the gelled nutritional composition has an energy density of about 800 kcal/l to about 1200 kcal/l.

20 26. A method according to claim 22 in which the gelled nutritional composition has a viscosity of about 5000 cp to about 40000 cp.

27. A method according to claim 22 in which the protein source provides about 10% to about 25% of the energy of the gelled nutritional composition.

25 28. A method according to claim 22 in which the carbohydrate source provides about 75% to about 90% of the energy of the gelled nutritional composition.

30 29. A method for providing supplemental nutrition to a child, the method comprising administering to the child a gelled nutritional composition which contains a protein source including gelled whey protein; a carbohydrate source; minerals; and vitamins.



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(57) Abstract: A nutritional supplement in the form of a gelled nutritional composition. The composition contains gelled whey protein; a carbohydrate source; minerals; and vitamins. The composition may have a viscosity of about 5000 cp to about 40000 cp and an energy density of about 800 kcal/l to about 1200 kcal/l. The composition is suitable for dysphagia patients, children and athletes.

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I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

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I hereby claim the benefit under 35 U.S.C. Section 120 of any United States application(s), or Section 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C.F.R., Section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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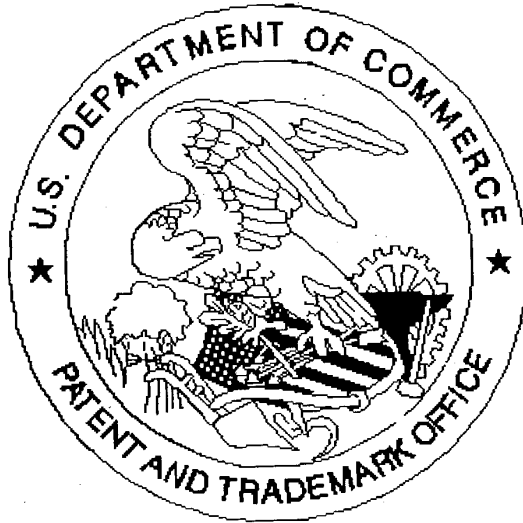
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